UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF JAIME L. SEPULVEDA-TORO, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") submit this memorandum and attached exhibits in opposition to Plaintiffs' motion to limit the opinions and testimony of Jaime L. Sepulveda-Toro, M.D.

Plaintiffs adopt their motion and arguments from Wave 1 in moving to exclude in Wave 5 certain expert testimony of Dr. Sepulveda regarding Ethicon's mesh devices. Yet the Court already ruled on Plaintiffs' Wave 1 motion regarding Dr. Sepulveda and rejected nearly all of Plaintiffs' arguments. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4536872 (S.D.W. Va. Aug. 30, 2016). The only exceptions to this sweeping denial were Plaintiffs' arguments regarding Dr. Sepulveda's testimony on Ethicon's warnings (which the Court accepted in part) and his testimony on certain scientific studies (which the Court reserved ruling on until trial).[1]

[1] The Court did not address Plaintiffs' attack on Dr. Sepulveda's opinion that fellow pelvic floor surgeons would know of the FDA's 2008 Public Health Notice on surgical pelvic mesh or Plaintiffs' request to exclude his opinion that the TVT-O's design accounts for anatomical considerations. (Plaintiffs' Mem. (Dkt. No. 2018) at 7, 14). For the reasons set forth below, Plaintiffs' arguments here are without merit and should be rejected.

Ethicon is mindful of this Court's warning not to assume that a previous *Daubert* ruling is controlling as the Court may be faced "with a different record". *Id.* at *1. Yet in this case, Plaintiffs do not (and cannot) point to any new opinions or testimony by Dr. Sepulveda that might cause the Court to adopt a different course in Wave 5. Instead, Plaintiffs essentially adopt the same arguments and these should suffer the same fate as in Wave 1. Moreover, their arguments with respect to Dr. Sepulveda's opinions on Ethicon's warnings and brochure if narrowly construed, as the Court framed them in Wave 1, should also be denied as moot. Dr. Sepulveda is not being offered to testify as to the legal standard of what should or should not be included in the relevant IFUs or patient brochures.

Instead, he will testify: (a) as to the risks and complications known by surgeons to be common with pelvic surgeries; (b) that mesh surgery has the same risks and complications with only a few, unique exceptions; and (c) those complications and events unique to mesh are covered by the IFU. Those are the relevant facts under the applicable legal standard, as previously found by this Court. Dr. Sepulveda's extensive research of the scientific literature and experience as a surgeon and instructor qualify him to testify to these facts. This is also consistent with this Court's ruling that urogynecologists, like Dr. Sepulveda, may testify as to specific risks of implanting mesh and whether those risks appeared in the IFU.

For these reasons, as detailed further below, Plaintiffs' motion should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

I. Plaintiffs' attempt to preclude Dr. Sepulveda from testifying that the subject devices are safe and effective rests on mischaracterizations of his opinions and testimony.

In challenging the reliability of Dr. Sepulveda's opinions that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are safe and effective, Plaintiffs distort and mischaracterize his deposition testimony.[2] Indeed, after reviewing these exact same arguments in Wave 1, the Court held that each were "wholly devoid of merit." *In re: Ethicon*, 2016 WL 4536872, at *3. In so doing, the Court found that:

- Plaintiffs' claim that Dr. Sepulveda agreed with the FDA's classification of Gynemesh PS, Prolift, and Prosima as high risk devices was "based on the plaintiffs' mischaracterization of Dr. Sepulveda-Toro's deposition testimony";
- Plaintiffs' argument that Dr. Sepulveda stopped using these devices was "irrelevant because Dr. Sepulveda-Toro merely stopped using the products because they were not on the market"; and
- Plaintiffs' claim that Dr. Sepulveda could not name at his deposition certain five-year studies on SUI products was "meritless because [his] report includes citations to long-term studies, so it does not matter whether Dr. Sepulveda-Toro could recall the studies during his deposition."

In re: Ethicon, 2016 WL 4536872, at *3.

The facts and arguments here remain unchanged. With the record the same as in Wave 1, Plaintiffs' request to exclude Dr. Sepulveda's opinions that the devices at issue are safe and effective should once again be denied.

II. Dr. Sepulveda may testify regarding the FDA's 2008 Public Health notice.

Dr. Sepulveda's opinion that the FDA's 2008 Public Health Notice on surgical pelvic mesh would have been common knowledge to other pelvic floor surgeons is not, as Plaintiffs claim, "pure conjecture." (Plaintiffs' Mem. (Dkt. No. 2018) at 7). In arguing otherwise, Plaintiffs ignore Dr. Sepulveda's experience as an instructor, memberships in multiple professional societies, and numerous other interactions with fellow clinicians. Although the

[2] He also has a third general report that addresses TVT, TVT-O, and, in particular, TVT Secur. Although this report contains similar opinions, Plaintiffs do not cite to it or appear to be challenging it.

Court did not in its Wave 1 ruling specifically address Plaintiffs' argument here, Ethicon respectfully requests that it do so now and reject Plaintiffs' request to exclude this testimony.

Dr. Sepulveda has taught surgeons on polypropylene midurethral slings for numerous years and over 500 physicians have watched him place a midurethral sling in his operating room. (Plaintiffs' Motion, Ex. B at 1-2). He is a member of the American Urogynecologic Society, American Urogynecologic Association, International Urogynecology Association, and the International Continence Society and a fellow of the American College of Obstetrics and Gynecology and the American College of Surgeons. (*Id.*). Indeed, as he states in his report, all of "[t]he professional education activities provided the opportunity to exchange knowledge among surgeons." (*Id.* at 18).

As a result, Dr. Sepulveda has interacted for multiple years on a near constant basis with fellow practitioners as both a surgeon and instructor regarding the devices at issue. These experiences uniquely qualify him to say whether the contents of the 2008 Public Health Notice would have been common knowledge to his fellow surgeons. *See Kumho Tire Co., Ltd. V. Carmichael*, 526 U.S. 137, 156 (1999) (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience"); *Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community"); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.,* 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *U.S. v. Articles of Device*, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (FDA offered affidavit in misbranding case) ; *Daiichi Pharm. Co. v. Apotex, Inc.*, 380 F. Supp. 2d 478, 489 (D.N.J. 2005) (relying on expert

testimony regarding what an ordinary person skilled in the art would not have known at the relevant time).

It is also interesting to note that Plaintiffs fail to address his contemporaneous writing on this subject in 2008 at the time of the Public Health Notice, which was produced in this litigation. (*See* 10/22/08 Email (ETH.MESH.07383398-401) (attached as Ex. A)). This writing was also reproduced in its entirety within pages 31-37 of his TVT Secur General Report, which pertains to his IFU opinions, complications, and his activities as an instructor. Upon viewing this documentation, it is clear that Plaintiffs' attempt to preclude Dr. Sepulveda from offering such testimony is disingenuous and should therefore be rejected.

III. Dr. Sepulveda may testify to the adverse event risks known by pelvic floor surgeons and that Ethicon's warnings cover the adverse events said to be unique to mesh.

In its Wave 1 decision on Dr. Sepulveda, the Court distinguished between the types of opinions urogynecologists may offer on Ethicon's IFUs. These physicians, like Dr. Sepulveda, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *See In re Ethicon, Inc.*, 2016 WL 4536872, at *3. Conversely, they "must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *Id*. On this basis, the Court precluded Dr. Sepulveda from testifying in Wave 1 cases about "what an IFU should or should not include." *Id.*

Ethicon is not challenging this ruling as Dr. Sepulveda does not intend to opine that Ethicon's IFUs should or should not have included certain risks as a matter of law. So, to the extent that Plaintiffs seek only to preclude him from offering this specific opinion, as the Court's Wave 1 ruling states, their motion should be denied as moot.

In support of their failure-to-warn claims, Plaintiffs offer experts who have identified a host of alleged risks and complications to mesh surgery that they contend do not appear on the

relevant IFUs. In response, Ethicon is offering physicians, like Dr. Sepulveda, to testify as to which of those risks and complications identified by Plaintiffs' experts are known by surgeons to be common with all pelvic surgeries and, conversely, whether those risks and complications that are truly unique to mesh surgery are covered by the IFU.

This testimony is critical to Ethicon's "common knowledge" defense under the applicable legal standard establishing the risks and complications that needed to be included in the IFUs. Moreover, this testimony is consistent with this Court's Wave 1 ruling that urogynecologists may testify about the risks of implanting mesh and whether they are discussed in the IFU. *In re Ethicon, Inc.*, 2016 WL 4542054, at *3. It also is consistent with the Court's ruling in *Huskey v. Ethicon, Inc.*, that Plaintiffs' expert, Dr. Jerry Blaivas, "need not be an expert on product warnings per se" but "[r]ather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and ***whether those risks were adequately expressed on the TVT-O's IFU***." 29 F.Supp.3d 691, 719 (S.D. W. Va. 2014) (emphasis added). Dr. Sepulveda is well-qualified to offer this testimony based on both his extensive experience and research. Also, this is a proper subject for expert testimony as numerous courts have held that experts may testify as to whether certain risks associated with a device are commonly known by foreseeable users.

The legal standard. Dr. Sepulveda's testimony on Defendants' IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product

users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of persons whose use is at issue in the particular case. *Johnson v. American Standard, Inc.*, 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulations say that information may be omitted from labeling: "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbott Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The IFUs for Gynemesh PS, Prolift, and Prosima state that "[u]sers should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing" the devices. (Plaintiffs' Motion, Ex. B at 16). The TVT IFU says "[u]sers should be familiar with surgical techniques for bladder neck suspension

and should be adequately trained in implanting the TVT system" and that it "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)." (ETH.MESH.00875456 (attached as Ex. B)). The TVT-O IFU says it should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device." (ETH.MESH. 02340829 (attached as Ex. C)).

So the important question with respect to the plaintiffs' failure to warn claim is what "hazards" are "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery at the time the device was implanted. Ethicon had no duty to warn of adverse events "commonly known" to those surgeons. Its duty was to warn of adverse events that were unique to the new devices, or, at the very least, unique to the use of mesh.

Evidence regarding the risks and complications that were commonly known to pelvic surgeons is also properly provided through expert testimony. Experts may testify as to the knowledge common within a profession or community. *See Flannery*, 2008 WL 77723, at *2; *Cruz-Vargas,* 348 F.3d at 277; *Articles of Device*, 426 F. Supp. at 370. The same holds true here. The proper vehicle for offering evidence as to which of the risks and complications identified by Plaintiffs were already commonly known by surgeons is through physician-experts, like Dr. Sepulveda. Indeed, this Court has previously held that physicians, like Dr. Sepulveda, may testify as to the risks of mesh surgery known by fellow surgeons.

Dr. Sepulveda's qualifications. Dr. Sepulveda is well-qualified to render such an opinion. He has over 20 years of practice in the field and has performed over 2,000 synthetic midurethral slings since 1998. (Plaintiffs' Motion, Ex. B at 1-2). Moreover, unlike some of the

experts Plaintiffs offer regarding the adequacy of Defendants' warnings, Dr. Sepulveda has actually used the devices, IFUs, and brochures at issue in his practice.[3] (*Id.* at 2).

In addition, as an instructor for Ethicon, he has conducted surgical anatomy laboratories with the use of models and cadavers, consensus conferences among experienced users, surgical demonstrations in the operating room, and didactic lectures. (*Id.* at 18; Plaintiffs' Motion, Ex. C at 22; 10/22/08 Email (ETH.MESH.07383398-401)). In this professional education role, Dr. Sepulveda covered and taught to fellow surgeons the IFUs at issue. (Sepulveda 3/30/16 Dep. Tr. (attached as Ex. D) 275:24 – 276:16). As he testified at his deposition, the IFU was taught at "every single lab" and that "as a preceptor or as teacher, you need to know that IFU by – by steps and know not only what it says, but what it really says in terms of mechanics." (*Id.*). Dr. Sepulveda further noted in his reports that "[a]ll these activities offer the opportunity to address the complications and details of the surgery along with the interpretation of the IFU." (Plaintiffs' Motion, Ex. B at 18; Plaintiffs' Motion, Ex. C at 22).

His opinion also rests on literature and professional association statements. Yet Dr. Sepulveda's opinion is not based solely on his lengthy and distinguished clinical experience. Instead, Dr. Sepulveda also relies on an in-depth review of the medical literature, as outlined in his reports. These include numerous studies comparing mesh to non-mesh surgery.[4] He has also

[3] Plaintiffs incorrectly suggest that Dr. Sepulveda is not familiar with the IFU for TVT because he testified that the last time he reviewed it was six years ago. (Plaintiffs' Mem. (Dkt. No. 2018) at 8). Plaintiffs fail to note that Dr. Sepulveda also testified that he is aware of the contents of the IFUs and his substantial experience with the IFUs, as detailed above, proves the point. (Sepulveda 3/30/16 Dep. Tr. 122:8-22).

[4] These include: Carey M, Higgs P, Goh J, Lim J, Leong A, Krause H, Cornish A. *Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial*, BJOG. 2009 Sep.116(10):1380-6; Withagen MI, Milani AL, den Boon J, Vervest HA, Vierhout ME. *Trocarguided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial*, Obstet Gynecol. 2011 Feb;117(2 Pt 1):242-50; Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C; Nordic Transvaginal Mesh Group, *Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse*, N Engl J Med. 2011 May 12;364(19):1826-36. doi: 10.1056/NEJMoa1009521. Erratum in: N Engl J Med. 2013 Jan 24; 368(4):394; Sokol AI, Iglesia CB, Kudish BI, Gutman RE, Shveiky D, Bercik R, Sokol ER, *One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse*, Am J Obstet Gynecol. 2012 Jan;206(1):86.e1-9; Halaska M, Maxova K, Sottner

reviewed and relies on literature on dyspareunia and other complications common to pelvic floor surgeries.[5] Conversely, Dr. Sepulveda has also reviewed literature on complications unique to mesh surgery, such as mesh exposure.[6] Further, he has reviewed and relies upon literature on TVT and TVT-O, including long term studies on the devices' efficacy and complications.[7]

In his opinion, complications of traditional non-mesh surgery include voiding dysfunction, permanent retention of urine, catherization, de novo urge incontinence, urinary tract infections, hernias, hematomas, fascial sling exposure, and granulomas. (Plaintiffs' Motion, Ex. B at 4-12; Plaintiffs' Motion, Ex. C at 5-7). The use of native tissue surgical repair for prolapse has been associated with high rates of recurrence of 30% to 50%. (Plaintiffs' Motion, Ex. B at 5). The Burch procedure has been shown to increase the risk of vaginal prolapse and also cause pain, sexual dysfunction and dyspareunia. (Plaintiffs' Motion, Ex. C at 5-6).

O, Svabik K, Mlcoch M, Kolarik D, Mala I, Krofta L, Halaska MJ, *A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse*, Am J Obstet Gynecol. 2012 Oct;207(4):301.e1-7; El-Nazer MA, Gomaa IA, Ismail Madkour WA, Swidan KH, El-Etriby MA, *Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study*, Arch Gynecol Obstet. 2012 Oct;286(4):965-72; Qatawneh A, Al-Kazaleh F, Saleh S, Thekrallah F, Bata M, Sumreen I, Al-Mustafa M, *Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: a prospective randomised study*, Gynecol Surg 2013; 10:79–85; Svabik K, Martan A, Masata J, El-Haddad R, Hubka P., *Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial*, Ultrasound Obstet Gynecol. 2014 Apr;43(4):365-71; Dos Reis Brandão da Silveira S, Haddad JM, de Jármy-Di Bella ZI, Nastri F, Kawabata MG, da Silva Carramão S, Rodrigues CA, Baracat EC, Auge AP, *Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment*, Int Urogynecol J.2015 Mar;26(3):335-42. (*See* Plaintiffs' Motion, Ex. B at 8, n. 22 (citing all of the studies listed above)).

[5]These include: Francis WJ, Jeffcoate TN, *Dyspareunia following vaginal operations*, J Obstet Gynaecol Br Commonw. 1961 Feb; 68:1-10; Lowman JK, Jones LA, Woodman PJ, Hale DS, *Does the Prolift system cause dyspareunia?*, Am J Obstet Gynecol. 2008 Dec;199(6):707.e1-6. (*See* Plaintiffs' Motion, Ex. B at 12, ns. 25 and 26 (citing and discussing these studies)).

[6] These include: Murphy M, Holzberg A, van Raalte H, Kohli N, Goldman HB, Lucente V; Pelvic Surgeons Network, *Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse,"* Int Urogynecol J. 2012 Jan;23(1):5-9; Benbouzid S, Cornu JN, Benchikh A, Chanu T, Haab F, Delmas V, *Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up*, Int J Urol. 2012 Nov;19(11):1010-6. (*See* Plaintiffs' Motion, Ex. B at 12-13 ns. 31 and 33 (citing and discussing these studies)).

[7] (*See* Plaintiffs' Motion, Ex. C at 11 ns. 27 (citing numerous, long-term studies on TVT and TVT-O)).

With mesh surgery, there are fewer wound complications than with non-mesh surgery and there are usually mesh exposures which can be conservatively managed on an outpatient basis. Studies show that anatomic superiority of Gynemesh PS and Prolift and improvements in bowel, prolapse, sexual function, urinary incontinence or urgency, voiding difficulty, and vaginal pressure/bulge. (Plaintiffs' Motion, Ex. B at 9). In addition "[t]he most recent Cochrane Review demonstrates that there are lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination with permanent polypropylene mesh like Gynemesh PS compared to native tissue repair and there is no difference in repeat surgery for incontinence or dyspareunia versus native tissue repair." (*Id.* at 10). Studies of Prosima have produced similar results. (*Id.* at 15). Also, studies and "[s]urgical experience made clear that patients treated with TVT had less voiding dysfunction, less wound complications and less retention than the historic numbers from patients treated with pubovaginal slings, needle procedures or open retropubic procedures." (Plaintiffs' Motion, Ex. C at 13-14).

"Mesh exposure is the only unique complication with Gynemesh PS and and Prolift," but, "[i]n many cases it can be treated conservatively with estrogen or a simple office procedure to excise the exposure." (Plaintiffs' Motion, Ex. B at 12). Also studies have demonstrated a low mesh exposure rate for patients, including a study with a 54 month follow-up that reported an 85% cure rate, no reoperations for recurrence, a 5.3% mesh exposure rate (of which two cases were excised and two resolved with estrogen), and no infections. (*Id.* at 13). The complications unique to synthetic slings are erosions and extrusions. (Plaintiffs' Motion, Ex. C at 17-20). Yet studies have shown low complication rates, and, in at least one study, none of the patients having any sign of tissue reaction, erosion, or tape protrusion at their 5-year follow-up. (*Id.* at 20).

The risks of dyspareunia and hematomas are well known to surgeons performing stress incontinence repairs and are not limited to mesh surgeries. (Plaintiffs' Motion, Ex. B at 11-13). Other complications with mesh slings are of the same type as those with non-mesh surgery. (*Id.* at 8-14). Studies have shown a cure rate for mesh surgeries in the range of 85% or higher, with a much lower cure rate shown for non-mesh surgeries. (Plaintiffs' Motion, Ex. B at 8-9, 13; Plaintiffs' Motion, Ex. C at 20).

Dr. Sepulveda's Opinions. Based on these facts, it is Dr. Sepulveda's opinion that the IFUs for Gynemesh PS, Prolift, Prosima, TVT, and TVT-O specifically identify, among other things, those risks that are unique to mesh surgery. (Plaintiffs' Motion, Ex. B at 18, 39; Plaintiffs' Motion, Ex. C at 22-23). So, Dr. Sepulveda opines that "[m]esh exposure is the only unique complication" with mesh devices and that "other wound complications occur without the use of mesh." (Plaintiffs' Motion, Ex. B at 12). In addition, he opines that:

> The complications such as tissue contraction, scarring, pelvic pain, and dyspareunia are well-known complications that can occur with any pelvic floor surgery, including Prolift. The complication of mesh erosion or exposure is a wound complication like those seen with non-synthetic mesh repair and is not caused by a defect in the mesh. These are well-known complications that surgeons learn in medical school, residency, fellowship, through continued medical education, peer-reviewed literature, discussions with colleagues, and the FDA Public Health Notifications.

(*Id.* at 18).

This is testimony that directly addresses the appropriate legal standard, which cannot be applied without evidence of what is "commonly known" to the class of foreseeable users about the risks of the surgery. Because it is consistent with the applicable legal test, it "fits" this case whether or not Dr. Sepulveda himself can testify what, as matter of law, need or need not be included in Ethicon's IFUs and patient brochures.

IV. Dr. Sepulveda may testify that the devices are not defective.

Plaintiffs' contention in their Wave 1 motion that Dr. Sepulveda is unqualified to say that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are not defective rests on their erroneous characterization of this as a "design" opinion. (Plaintiffs' Mem. (Dkt. No. 2018) at 8-9). Yet, as this Court held in response to Plaintiffs' same argument in Wave 1, the mere fact that Dr. Sepulveda may have used the word "design" does not transform his opinions into ones concerning the design of the TVT and TVT-O. *See In re Ethicon, Inc.*, 2016 WL 4536872, at *3. Thus, the Court concluded that "Dr. Sepulveda-Toro has not expressed any opinions about the process of designing a product" and denied Plaintiffs' motion as moot. *Id.*

This same ruling should apply here. Plaintiffs' do not identify any additional opinions, testimony, or case law in support of their arguments. Instead, as noted above, they simply adopt their same briefing from Wave 1. As the record here is unchanged, Plaintiffs' motion to exclude Dr. Sepulveda's "design" opinions should once again summarily be denied as moot.

V. Dr. Sepulveda may testify as to the value (or lack thereof) in explants and offer critiques of Plaintiffs' experts' pathological opinions.

Plaintiffs wrongly seek to exclude certain testimony by Dr. Sepulveda because he is not a pathologist. In response to these exact same arguments in Wave 1, the Court denied Plaintiffs' motion after finding that Dr. Sepulveda has "extensive experience studying the relevant part of the body, both through surgery and through the dissection of hundreds of cadaver specimens" and that "[h]e has also written a manual on dissection and how to make the best specimens." *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. The Court also held that Plaintiffs failed to provide sufficient specificity of the critiques of Plaintiffs' pathologists by Dr. Sepulveda that they contend should be excluded. *Id.*

Plaintiffs' arguments should again suffer the same fate. Although Dr. Sepulveda is not a pathologist, he has a wealth of relevant experience that qualifies him to offer the opinions at

issue. The record here is the same as Plaintiffs have provided no new facts or arguments that might dictate a different result. Plaintiffs' request to exclude Dr. Sepuvleda's testimony should therefore be rejected.

VI. Dr. Sepulveda may testify as to the general number of studies done on the devices and offer opinions on degradation.

Plaintiffs' overwrought characterization of Dr. Sepulveda's reference to the general number of studies performed on the devices at issue as "outlandish" and "conjecture" do not support any limits on his testimony. (Plaintiffs' Mem. (Dkt. No. 2018) at 10-11). In response to these same arguments in Wave 1, the Court reserved ruling "until the evidence may be evaluated firsthand at trial." *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. Ethicon asks that the Court adopt the same course here or simply reject Plaintiffs' arguments outright.

As detailed above, Dr. Sepulveda cites to and discusses for pages of his reports numerous studies of Gynemesh PS, Prolift, Prosima, TVT, and TVT-O. *See supra.* His list of resources relied upon contains even more. (List of Materials Relied Upon For Gynemesh PS, Prolift, Prosima, TVT, and TVO-O Reports (attached as Ex. E)). Dr. Sepulveda has performed an exhaustive review of the relevant scientific literature and not just for his work in this case, but also in his daily practice. (Plaintiffs' Motion, Exs. A at 3 (noting his regular reading of mesh research) and B at 2 (noting his regular reading of sling research)). He is more than qualified and able to offer opinions as to the general numbers of studies performed on the devices.

Plaintiffs' attempt to exclude Dr. Sepulveda's opinions regarding degradation of the devices is equally without merit. In the portion of the testimony cited by Plaintiffs, Dr. Sepulveda does not disclaim sufficient expertise to testify regarding degradation of polypropylene. Rather, his testimony is entirely consistent with his reliance on studies (or the lack thereof) performed by others regarding degradation. As Dr. Sepulveda made clear in an

earlier deposition, he has reviewed the scientific literature and not found any that support a theory of degradation. (Sepulveda 3/20/16 Dep. Tr. 176:5 – 177:14 (testifying that "there's no evidence" of degradation and that "degradation has not been defined in a reproducible scientific way to have – to be present, or if present, to have any consequences in clinical outcomes") and 282:14 – 284:21 (testifying that he had reviewed the various studies referenced by Plaintiffs' counsel and others and that "I have not seen one yet that proves degradation with any definition that I've given of degradation")). He has also reviewed the data cited by Plaintiffs' experts and finds them without merit:

> These case reports and case series of explants lack reliability and one cannot draw any causal inference from them or extrapolate their reported SEM findings to the larger population. In the referenced Clave study there were several methodologic flaws. Moreover, only a minority of the explants were reported to have surface cracking and degradation and oxidation were not shown on chemical analyses. While the purported surface changes were hypothesized to lead to adverse clinical outcomes, these hypotheses have not been confirmed.

(Plaintiffs' Motion, Ex. B at 20)

Moreover, the Court has previously found that a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him to opine on "how the product reacts inside the body."[8] Like the physicians in those cases, Dr. Sepulveda is a skilled urogynecologist with 24 years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. *See supra.* He has performed thousands of stress incontinence surgeries, and has placed the vast majority of the slings through the transobturator route. His opinions are premised upon clinical observations

[8] *Winebarger v. Bos. Sci. Corp.,* No. 2:13-CV-28892, 2015 WL 1887222, at *26 (S.D. W. Va. Apr. 24, 2015); *see also Trevino,* No. 2:13-CV-01617, 2016 WL 1718836 at *4-5 (rejecting challenge to practicing urologist whose "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction").

from performing thousands of procedures involving mesh. (Plaintiffs' Motion, Ex. A at 1-2). Accordingly, Dr. Sepulveda is well-qualified to offer opinions regarding degradation.

VII. Dr. Sepulveda may testify that the design of TVT-O takes into account anatomical considerations.

Plaintiffs incorrectly argue that Dr. Sepulveda needed to have been involved in the design process in order to opine that the TVT-O's design accounts for anatomical considerations, in particular the hammock of the suburethra and the periurethral tissue. Although the Court did not in its Wave 1 ruling specifically address Plaintiffs' argument here, Ethicon respectfully requests that it do so now and reject Plaintiffs' request to exclude this testimony.

As detailed above, Dr. Sepulveda has performed numerous dissections and even written a manual instructing others on how to perform dissections and make use of specimens. Indeed, the Court acknowledged in this experience when holding that Dr. Sepulveda is qualified to testify as to the value of explanted materials. *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. When instructing in Ethicon's cadaver labs, Dr. Sepulveda necessarily broke-down for fellow surgeons the anatomical effects of mesh devices. Indeed, he notes in his TVT and TVT-O report that he has "dissected the [urethral] area in cadavers extensively and been able to confirm the support to the urethra in this area." (Plaintiffs' Motion, Ex. C at 8; *see also* 8 n. 15-17 (anatomical studies), 20 (anatomic considerations of the TVT-Os design) and 20 n. 66 (*citing* relevant literature)). Accordingly, Dr. Sepulveda need not have been present at the design of TVT-O to opine as to whether it is consistent with the anatomical considerations he has witnessed first hand in countless dissections. Plaintiffs' request to exclude such testimony should be denied.

VIII. Dr. Sepulveda may testify that mechanical cut tape is not defective.

Plaintiffs misconstrue the scientific literature and evidence in trying to exclude Dr. Sepulveda's testimony that mechanical cut tape is not defective. In response to these same

arguments in Wave 1, the Court held that Plaintiffs' "objections [are] insufficient to credibly call into question the reliability" of Dr. Sepulveda's opinion and therefore denied Plaintiff's motion. *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. Plaintiffs' effort to exclude this same testimony should once again be rejected. Plaintiffs do not identify any new facts or arguments that would alter the record before the Court. Instead, the record remains the same and Plaintiffs' motion should again be denied. [9]

CONCLUSION

Dr. Sepulveda's distinguished and lengthy career, together with his extensive review of the scientific literature and many interactions with fellow colleagues, qualifies him to offer the opinions at issue. His methodology of relying on these experiences and interactions and his review of the literature in reaching his conclusion is sound. The Court should enter an order denying Plaintiffs' motion to limit the opinions and testimony of Dr. Sepulveda.

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[9] Also, Plaintiffs' request to exclude use of the term "gold standard" remains moot, as this Court held in its Wave 1 ruling. *See Ethicon*, 2016 WL 4536872, at *4. Dr. Sepulveda testified that he prefers "clinical standard" rather than "gold standard," which he views as a marketing term. (Ex. D at 74:15 – 75:6). Finally, Plaintiffs misread Dr. Sepulveda's report in claiming he opines that the Section 510(k) process demonstrated TVT's tolerability and safety. He instead cites to a 2001 study by Folconer, Soderberg, Blomgren, and Ulmsten in support of his opinion that "tolerability and safety has been proven by the predicate device and graft, in this case the TVT Prolene polypropylene mesh tape." (Plaintiffs' Motion, Ex. C at 24 n. 72). Dr. Sepulveda does not intend to opine on the Section 510(k) process in a manner inconsistent with this Court's prior rulings

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on August 28, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones